Guidance for Petitioning the Environmental Protection Agency Under Section 21 of the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice provides guidance for preparing citizens' petitions under section 21 of the Toxic Substances Control Act (TSCA). Petitioners' use of this guidance will assist the Environmental Protection Agency to evaluate properly citizens' petitions within the 90-day review mandated by the statute. This guidance will also assist petitioners in effectively presenting their case to EPA with the most pertinent available support material.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Environmental Protection Agency, Rm. E-543, 401 M Street, SW., Washington, DC 20460. In Washington, DC (554-1404). Outside the USA: (Operator-202-554-1404).

I. Background

Under section 21 of TSCA, any person may petition the Administrator of EPA to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 4, 6, or 8 or an order under section 5(e) or 6(b)(2) of TSCA. Within 90 days after a petition has been filed, the Administrator must either grant or deny it. The Administrator may hold a public hearing or may conduct such investigation or proceeding as deemed appropriate in order to determine whether or not the petition should be granted. If the petition is denied, the Administrator must give the reasons for denial in the FEDERAL REGISTER. If granted, the Administrator must promptly initiate an appropriate proceeding in accordance with section 4, 5, 6, or 8.

Twenty-seven section 21 petitions have been submitted since 1978, or about three per year. Six of those have been granted, of which five were related to asbestos control.

Within the past 2 years the Agency has received two petitions that set precedents in terms of both the scope of relief requested, and in the amount of EPA resources required to respond. These two petitions, requesting relief for a number of multimedia pollution problems, were submitted with extensive support data. This guidance is intended to help focus future section 21 data submissions directly in support of the petition, thereby eliminating unnecessary efforts by petitioners, and facilitating Agency response.

To understand the requirements of section 21, it is necessary to understand the substance of the four key sections of TSCA under which section 21 relief may be sought, and the criteria which must be met to initiate action under those sections. These factors are discussed in the following sections.

II. Guidance

While the Agency will consider all petitions ified pursuant to section 21 irrespective of adherence to guidance contained herein, petitioners are encouraged to follow these suggestions in order both to present their case effectively and to faciliatate the Agency's timely evaluation and response. All items may not be applicable to a specific petition. This guidance is simply intended to serve as a checklist to enable petitioners to present their case as persuasively and comprehensively as possible.

A. GENERAL CONSIDERATIONS

1. Information about the petitioner. Petitioners should state their name, address, phone number, whom to contact for further information and, if an organization, the nature of its purpose and membership.

2. Description of the relief requested. In addition to specifying the TSCA section under which relief is sought (i.e., section 4, 5, 6, and/or 8), petitioners should describe as completely as possible how the action requested would solve the problem. This requirement is discussed in more detail under Unit II Special Considerations, below.

3. Description of the pmblem. In order to take any actions under TSCA sections 4, 5 or 6, EPA must make a finding regarding the potential for or presence of unreasonable risk. This finding must be made not only when a new regulation is issued, but also when an existing regulation is amended or repealed. The term "unreasonable risk" is not defined in the statute, but the legislative history indicates that Congress intended EPA to balance the benefits derived from risk reduction against the social and economic costs incurred, taking into account such factors as the extent and magnitude of

risk posed; the societal consequences of removing or restricting use of products; availability and potential hazards of substitutes; and impacts on industry, employment, and international trade. To do this, EPA must have the relevant data. The Agency therefore encourages petitioners to provide as much information as possible in each of the following areas.

(a) The nature and severity of harm (toxicity) to humans or the environment from the chemicals of concern. This information indicates a chemical's potential to induce cancer, gene mutations, birth defects, other long-term effects, or such acute effects as neurotoxicity, renal toxicity, hepatotoxicity or irreversible ocular damage. These findings are usually made on the basis of laboratory tests on animals, studies of human populations (epidemiological studies), medical case reports, or by analogy to similar, known toxic chemicals or other relevant studies.

(b) Exposure. Exposure data reflect the actual or potential release of a chemical substance to the environment or its actual or potential contact with humans. It may be assessed by qualitative or quantitative estimation of the magnitude, frequency, duration and route (i.e., inhalation, ingestion or skin absorption) of contact. Environmental exposures occur in air, water, soil, or affected ecosystems, and are influenced by such factors as persistence in the environment and bioaccumulation. Exposure assessments are typically based on monitoring data, simulation model estimates, or other measurements. In weighing exposure concerns, the Agency considers such factors as source; concentration levels and duration; populations or media exposed; and whether the scope of the assessment is global, national, regional, local, or site-specific. Exposure assessments are critical to rulemaking. Their purpose is to provide reliable data for risk assessments, which couple exposure and toxicity information. Exposure data are among the most difficult to obtain for both petitioners and the Agency. EPA has proposed guidelines as published in the FEDERAL REGISTER of November 23, 1984, (49 FR 46304) as an aid in carrying out exposure assessments.

(c) The extent of harm the chemicals of concern present or may present. This is the risk, which combines the nature and severity of harm (toxicity) with exposure to humans or the environment. This risk may range--in type, severity and immediacy--from thousands of short-term deaths resulting from massive acute exposure to chemicals as a consequence of an industrial disaster, to the longer-range consequences of typically continuous and low level exposure to carcinogens, mutagens, teratogens or other chronic toxicants. Since eventual rulemaking requires defensible assessments of risk based upon the toxicity of the chemical of concern and valid estimates of the extent of exposure, petitioners are encouraged either to (1) submit data that will permit the Agency to conduct a risk assessment, or (2) develop and submit a risk assessment together with the supporting data. The Agency has proposed a series of guidelines (49 FR 46294, Parts VII-X, November 23, 1984) as an aid to carrying out risk assessments for certain toxic effects.

(d) Risk reduction. This information indicates possible methods by which risk could be reduced, the degree of risk reduction that could be achieved, the costs of risk reduction methods, and the impacts of any regulation on the economy, small businesses and other affected entities. A basic principle embodied in TSCA is that the Agency must adopt regulatory requirements which impose the smallest social and economic burden possible, commensurate with the level of risk posed by the chemical in question. The Agency urges petitioners to submit any data that might facilitate this analysis.

B. SPECIAL CONSIDERATIONS

TSCA requires EPA to make certain findings, before regulating, depending upon the section of the statute to be used. Accordingly, the Agency's disposition of the petition will depend in large part upon the extent to which the submitted data (1) demonstrate or suggest that EPA wifi be able to make the relevant findings, and (2) indicate how the requested action would solve the problem. Below is a description of each section, and the findings the Agency must make prior to taking regulatory action.

1. Rules under section 4. Section 4 authorizes the Agency to promulgate rules that require manufacturers and/or processors to test specified chemical substances or mixtures in order to evaluate their adverse human or environmental effects. Such testing can be required for chemicals suspected of being harmful or that have substantially large

human or environmental exposures. Before requiring manufacturers and processors to conduct tests for health and/or environmental effects, the Agency must find: (1) That the chemical may pose an unreasonable risk of harm to health or the environment, or will be produced in substantial quantities which may result in significant human exposure or environmental release; (2) that insufficient data exist about the effects of the chemical to assess reasonably the impacts of its commercial production; and (3) that testing is needed to develop such data. EPA must also consider the potential economic impacts of mandatory testing before issuing section 4 requirements. In addition to providing data to support these findings, petitioners should explain how the results to be obtained from the requested section 4 test rule will help resolve petitioner's concerns.

2. Orders under section 5(e). Section 5(e) authorizes EPA to issue an order prohibiting or limiting the manufacture, processing, distribution in commerce, use or disposal of a new chemical substance when it has determined that existing information is insufficient to evaluate the substance's potential impact. Before issuing such an order, EPA must find (1) that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical, and (2) that the chemical may present an unreasonable risk of injury to health or the environment; or that the chemical will be produced in substantial quantities which may result in significant human exposure or substantial environmental release. Petitioners should provide whatever information is available to support the primary finding and either one or both of the secondary findings, and should indicate how the requested section 5(e) order would provide the desired relief.

3. Rules under section 6(a). Section 6(a) authorizes the Agency to impose a range of regulatory controls to prevent the production and use of a chemical substance or mixture from presenting unreasonable risks. Actions taken under section 6(a) must be imposed by rule, and include banning the substance or mixture entirely, prohibiting or limiting certain uses, or requiring labeling or other forms of public notification. To issue a rule under this section, EPA must find that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture presents or will present an unreasonable risk of injury to health or the environment. The key fin-clings relating to unreasonable risk must be made both when a new regulation is proposed, and when an existing regulation is amended or repealed. Petitioners should provide data to support these finds, and describe how the requested section 6 controls would help resolve the problem.

4. Orders under section 6(b)(2). Section 6(b)(2) authorizes the Agency to issue an order requiring a description of, and if necessary changes in, a company's quality control procedures in order to identify and remedy inadequacies or defects which cause a chemical substance to present an unreasonable risk to human health or the environment. Before issuing an order requiring a manufacturer or processor to submit a description of his quality control procedures, EPA must have a reasonable basis to conclude that the chemical is produced in a manner which unintentionally causes an unreasonable risk. Petitioners should provide any information bearing on that conclusion.

5. Rules under section 8. Section 8 authorizes the Agency, within reasonable bounds, to promulgate rules that require gathering, retaining, and reporting information concerning various factors relating to potential hazards posed by the production and use of chemical substances and mixtures, including the submission of relevant health and safety studies. Petitioners should explain the benefits to be derived from any requested section 8 rule.

C. ACTION UNDER OTHER STATUTES

Petitioners are encouraged to consider the risk involved, whether TSCA would most appropriately regulate that risk and, if so, to indicate why TSCA is preferable to other Federal statutes. The Agency emphasizes, here, that section 21 is specific to the particular sections (4, 6, 8, 5(e) and 6(b)) of TSCA enumerated in section 21, and is not appropriate for seeking relief under other sections of TSCA, other laws administered by EPA, or other Federal statutes. Before taking regulatory action under TSCA, EPA determines whether action under a statute or combination of statutes other than TSCA can adequately address the problem. Section 9(a) of TSCA requires EPA to refer unreasonable risks to another agency if EPA determines that such risks may be prevented or sufficiently reduced by action taken

under the other agency's law. Section 9(b) requires the Agency to act under one of its other laws unless it is in the public interest to act under TSCA.

Petitioners are particularly encouraged to include a discussion of actions that are being or could be undertaken by State and local authorities to provide the desired relief. Petitioners should describe, for example, any plans that local authorities may have to investigate or regulate the problems identified by petitioners. This discussion should clearly describe why planned or potential State or local actions are or would be inadequate and, to the extent possible, the actions beyond those available under current local authorities that would be necessary to solve the problem. Petitioners should indicate why and how Federal controls would be more effective than State or local controls. Since EPA will review the feasibility of State and local remedies in developing a response to the petition, review will be expedited if petitioners have explored this avenue in advance.

D. PRECONSULTATION

Persons considering filing petitions under section 21 of TSCA are asked first to seek relief, if appropriate, from local and State officials. Failing successful resolution at those levels, petitioners are encouraged, because of the effort required to marshal all relevant information and arguments, to consult with the Agency prior to filing a petition formally. This will enable petitioners to determine what information the Agency already has on the problem, what action it has taken or is taking, what particular information the Agency may need to make its decision, and what alternatives to Federal regulation may exist. Such preconsultations could result not only in strengthening the support documentation for petitions but, in some cases, in immediate resolution of petitioners' concerns.

E. EPA DECISIONS ON PETITIONS

Experience has shown that the Agency cannot always provide the relief sought by petitioners. The Agency must addresss each petition in terms of (1) magnitude of risk, (2) risk reduction achievable relative to cost, and (3) both of the above relative to existing regulatory priorities. Petitioners should, insofar as possible, provide data to support their contention that EPA should modify its existing regulatory agenda to accommodate their request. Although TSCA authorizes EPA to impose regulations applicable to specific geographical areas, petitioners requesting area-specific rules are encouraged to demonstrate the benefits to be derived relative to rules focused on the national level, or the possible implications of the proposed area-specific rule for future regulaton on a national level.

For further assistance in preparing and submitting citizens' petitions, prospective petitioners should contact the designated Toxic Substances Coordinator at any of the 10 EPA Regional Offices as follows:

Regional Offices

EPA, Region I, JFK Building, Room 2203, Boston, MA 02203, (617-223-7210);
EPA, Region II, 26 Federal Plaza, Room 900, New York, NY 10278, (212-264-2525).
EPA, Region III, 841 Chestnut Street, Philadelphia, PA 19107, (215-597-9800);
EPA, Region IV, 345 Courtland Street, N.E., Atlanta, GA 30365, (404-881-4727);
EPA, Region V, 230 South Dearborn Street, Chicago, IL 60604, (312-353-2000);
EPA, Region VI, 1201 Elm Street, Dallas, TX 75270, (214-767-2600);
EPA, Region VII, 726 Minnesota Avenue, Kansas City, KS 66101, (913-236-2800);
EPA, Region VIII, One Denver Place, 999 18th St., Suite 1300, Denver, CO 80202-2413, (303-293-1603);
EPA, Region IX, 215 Fremont Street, San Francisco, CA 94105, (415-974-8153);
EPA, Region X, 1200 Sixth Avenue, Seattle, WA 98101, (206-442-5810).

III. Conclusion

The guidance contained in this notice will help petitioners under section 21 of TSCA present their concerns to EPA with the maximum amount of relevant documentation, and will help expedite the Agency's evaluation within the 90-day review period.

Dated: November 1, 1985.

Lee M. Thomas,

Administrator.

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